REMARKS

Claim 23 has been amended. No new matter has been added by virtue of the amendments.

1. 35 U.S.C. §112 Rejection

Claims 23 and 60 have been rejected under 35 U.S.C.§112, second paragraph. In particular, the Office asserts that the claims use the term "the device" but that there is no limitation in the claim that describes the device.

Applicants respectfully traverse. Claim 23 reads as follows (emphasis added):

> 23. A method for treating an eye comprising:
> inserting into an eye a **device comprising a piercing member and a cannula insertable within the piercing member**, the cannula having a length longer than the length of the piercing member,
> wherein the piercing member is inserted into the sclera of the eye and the device is advanced transconjunctivally through the sclera of the eye and
> wherein the device is inserted into the eye by piercing the eye with the piercing member and advancing the piercing member into the eye.

Applicants respectfully submit that claim 23, as written, clearly sets forth elements describing the device. In particular, claim 23 states that the device comprises a piercing member and a cannula insertable within the piercing member. Thus, claim 23 claims a method wherein the device comprises both the piercing member and the cannula.

Claim 60 reads as follows (emphasis added):

> 60. A method for treating an eye comprising:
> inserting into an eye a **device comprising an outer member and a cannula within the outer member and within a piercing member**, the cannula having a length extending or extendable beyond the outer member distal end, wherein the device is inserted into the eye by piercing the eye with the piercing member and advancing the piercing member into the eye.

Applicants respectfully submit that claim 60, as written, clearly sets forth elements describing the device. In particular, claim 60 states that the device comprises an outer member, a piercing member and a cannula, wherein the cannula is within the outer member and within the piercing member.

Reconsideration and withdrawal of the rejection are respectfully requested.

2. 35 U.S.C. §102 Rejection

Claims 23-30, 32, 33-40, 42-44, 47-52, 54, 55, 58-65, 67-69 and 72-76 have been rejected under 35 U.S.C. §102(e) as being anticipated by Paques et al. (US Pub 2003/0171722). In particular, the Office Action states:

> Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gage [0053] allowing the puncture location to self-seal and having a flexible plastic tube therein [0087] to administer a therapeutic substance to the eye. The device is used to treat conditions such as a vascular occlusion [0039] by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally.

Applicants respectfully traverse the rejection.

Applicants' claims 23, 27 and 60 (the only pending independent claims) read as follows:

> 23. A method for treating an eye comprising:
> inserting into an eye a device comprising a piercing member and a cannula insertable within the piercing member, the cannula having a length longer than the length of the piercing member,
> wherein the piercing member is inserted into the sclera of the eye and the device is advanced transconjunctivally through the sclera of the eye, and
> wherein the device is inserted into the eye by piercing the eye with the piercing member and advancing the piercing member into the eye.

27. A method of treating an eye, comprising:
piercing the eye with a piercing member and inserting the piercing member into the eye, the piercing member having a proximal end and a distal end and a lumen defined therebetween;
advancing a cannula through the piercing member lumen;
guiding the cannula to a treatment site; and
treating the treatment site.

60. A method for treating an eye comprising:
inserting into an eye a device comprising an outer member and a cannula within the outer member and within a piercing member, the cannula having a length extending or extendable beyond the outer member distal end, wherein the device is inserted into the eye by piercing the eye with the piercing member and advancing the piercing member into the eye.

Paques et al. describes a device comprising a handpiece 2 having a distal end 2d **carrying a hollow needle 4**. The **needle 4** (or "piercing member", as described by the Office) **is sharpened at its distal tip for penetrating a blood vessel within the eye** (in particular, a blood vessel in the retina) [0039]. The distal end 2d further includes a passageway 12 for carrying an optical fiber 14 to illuminate the needle 4 during venous puncture [0042]. The handpiece 2 may further comprise a stabilizer 40 (e.g. a stabilizing plate) that is positioned against the retina to stabilize the needle 4 while penetrating a blood vessel in the retina [0046](Figs. 1 and 7). As shown in Fig. 1, the stabilizer 40 is located at the distal end 2d where the needle 4 projects outwardly beyond the distal end 2d.

During use, the needle 4 and the distal end 14d of the optical fiber 14 are inserted into the eye through a sclerotomy (surgical incision) [0048]. This is shown in Fig. 4. In particular, a substantial portion of the handpiece 2 is inserted into the eye through the sclerotomy. Specifically, the distal end 2d of the handpiece, which includes the needle 4, the passageway 12 carrying the optical fiber 14 and the stabilizer 40, is inserted into the eye through the sclerotomy. The distal end 2d is then advanced toward the blood vessel of the retina until the needle 4 pierces

the blood vessel. If the stabilizer 40 is used, the distal end 2d is advanced such that the stabilizer 40 is positioned against the retina to stabilize the needle 4 as it penetrates the blood vessel.

Thus, the Office's assertion that Paques describes a piercing member 4 with an outer diameter less than 25 gage, which would provide a self-sealing puncture is misleading and is taken out of context. While Paques does describe a piercing member, this piercing member is only a small portion of the device that enters the eye. According to Paques, the distal end 2d of the handpiece 2 enters the eye. This distal end 2b comprises the needle 4 ("piercing member"), the passageway 12 that carries the optical fiber 14, and the stabilizer 40. The needle **alone** does not enter the eye nor does it puncture the eye to provide an opening through which the device enters the eye. Rather, a sclerotomy is required to provide an opening through which the entire distal end 2d enters the eye. The needle 4 then pierces the blood vesse lwithin the eye. In any event, were the needle 4 used to form a puncture in the eye, the entire distal end 2d would not fit through the puncture (as required by Paques) because the needle 4 forms only a portion of the outer diameter of the distal end 2d. The distal end 2d is a much larger component of the device which "carries" the needle 4.

Thus, the needle 4 does not puncture the eye to provide a self-sealing opening through which the distal end 2d enters the eye. Rather, a sclerotomy (surgical incision) is made in the eye to provide an opening through which the distal end 2d (which includes the needle 4) enters the eye. Such incisions would typically require the use of sutures or other types of sealing techniques following removal of the device from the eye. Once the distal end 2d is inserted into the eye through the sclerotomy, it is advanced to the retina so that the needle 4 projecting from the distal end 2d can puncture a blood vessel **within the eye.**

As set out in claims 23, 27 and 60, Applicants' device is inserted into the eye by piercing the eye with the piercing member and advancing the piercing member into the eye. Paques, on the other hand, specifically describes a process wherein a sclerotomy (surgical incision) is made

in the eye to provide an opening through which the distal end 2d of the device, which includes the "piercing member" 4 (needle) enters the eye. The piercing member 4 (needle) forms only a portion of the outer diameter of the distal end 2d of the device which enters the eye. The piercing member 4 (needle) is later used to pierce a blood vessel within the eye **after** the distal end 2d has been inserted into the eye and advanced towards the retina. Thus, Paques clearly does not describe or suggest a method wherein the device is inserted into the eye by piercing the eye with the piercing member 4 (needle) followed by inserting the device into the eye.

Further, the Paques reference does not inherently describe a device or method in accordance with Applicants' claims 23, 27 and 60. As set forth above, the piercing member 4 (needle) of Paques forms only a portion of the Paques device which enters the eye. The entire distal end 2d, which includes, among other elements, the piercing member 4 (needle), enters the eye. The piercing member 4 (needle), thus, does not nor could it form the opening through which the distal end, which is much larger than the piercing member 4 (neelde), could enter the eye.

Thus, it is clear from the foregoing remarks that claims 23, 27 and 60 are not anticipated by the Paques et al. reference. As discussed, Paques et al. does not explicitly or inherently describe each and every element as set forth in the claims. Claims 24-26, 28-36, 38-59 and 61-76 depend from claims 23, 27 and 60 and, likewise are not anticipated by the Paques et al. reference.

In view thereof, reconsideration and withdrawal of the rejection are requested. See, for instance, *In re Marshall*, 198 USPQ at 346 ("[r]ejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art.").

3. 35 U.S.C. §103 Rejections

Claims 31, 45, 46, 56, 57, 70 and 71 have been rejected under 35 U.S.C §103(a) over Paques et al. (U.S. Patent Application 2003/0171722) in view of del Cerro et al. (U.S. Patent 5,409,457). In particular, the Office Action states:

> Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach withdrawal of fluid from the eye.
>
> Del Cerro et al. teaches a device comprising a tip for penetrating the subretinal region of the eye to deliver a therapeutic agent or withdraw fluid from the eye (column 4, line 31).
>
> It would have been obvious to one skilled in the art at the time of invention to withdraw fluid from the eye in order to reduce the pressure in the eye, as well as to deliver therapeutic fluid to treat the disease or injury, both actions possible with the syringe connected to the device of Paques.

Applicants respectfully traverse the rejection.

As set forth above, the Paques document does not describe or otherwise suggest a method for treating an eye wherein a device is inserted into the eye by piercing the eye with a piercing member and the piercing member is inserted into the eye, as Applicants disclose. Rather, Paques reported device and method requires the creation of a first incision through which the device is inserted into the eye. The device is advanced into the eye towards the retina and the piercing member 4 (needle), which forms only a portion of the device entering the eye, is subsequently used to pierce a blood vessel **within the** eye.

Further, the piercing member 4 (needle) of Paques does not **pierce the patient's eye** as required by Applicants' claims 23, 27, 60, 26, 47-48, 59 and 72-73. Rather, the piercing member 4 (needle) **pierces a blood vessel within the eye**. Thus, the piercing member does not provide an insertion site in the eye that is self-sealing following withdrawal of the piercing member from the eye. As set forth above, the incisions required for entry of the Paques device into the eye, as

reported by the Paques document, are not self-sealing but, rather, require the use of sutures or other sealing techniques to close the incision, in contrast to Applicants' claims 74-76.

The del Cerro document does not remedy these deficiencies. Further, Applicants respectfully submit that the del Cerro document does not advance the reported device transconjuctivally as recited in Applicants' claim 23 (See, e.g, Figure 2 of del Cerro) In fact, del Cerro specifically *teaches against* transcleral applications and states regarding other approaches (bold emphasis added):

> * * * they carry out sample delivery by penetrating an anterior part of the eye, i.e. via a transcorneal or **transcleral route**, which creates the risks of corneal ulceration, cataract formation, and other anterior penetration problems. (column 1, lines 36-41)

The insertion approach reported by del Cerro also is distinct from Paques. See, for instance, Fig. 4 of Paques compared with Fig. 2 of del Cerro. Clearly, then, the skilled worker would not have so carefully combined selected aspects of Paques and del Cerro as proposed by the instant rejection.

In view thereof, reconsideration and withdrawal of the rejection are requested.

Claims 41, 53 and 66 have been rejected under 35 U.S.C §103(a) over Paques (U.S. Patent Application 2003/0171722) in view of Bowman et al. (U.S. Patent 6,378,526). The Office Action asserts:

> Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach the delivery of steroids.

The rejection is traversed.

As set forth above, the Paques document does not describe or otherwise suggest a method for treating an eye wherein a device is inserted into the eye by piercing the eye with a piercing member and the piercing member is inserted into the eye, as Applicants disclose.

Further, the Bowman et al. document does not remedy the noted deficiencies of Paques et al. Reconsideration and withdrawal of the rejection are requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

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Respectfully submitted,

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